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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/680,988
Filing Date	10/07/03
First Named Inventor	Andrew R. Marks
Art Unit	1646
Examiner Name	to be assigned
Total Number of Pages in This Submission: 20	Attorney Docket Number: 5199-119

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance communication to Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  Return receipt postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Leslie Gladstone Restaino, Reg. No. 38,893
Signature	Leslie S. Restaino
Date	7/9/04

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

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Signature	Ping Xiao	Date	7/9/04

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JUL 12 2004
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Andrew Marks, et al.	Docket No.:	5199-119
Serial No.:	10/680,988	Examiner:	to be assigned
Filed:	October 7, 2003	Group Art Unit:	1646
Title:	**COMPOUNDS AND METHODS FOR TREATING AND PREVENTING EXERCISE-INDUCED CARDIAC ARRHYTHMIAS**		

July 9, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97(b)

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, applicant hereby notifies the U. S. Patent and Trademark Office of the following documents, which are listed on the attached PTO/SB/08A and PTO/SB/08B forms. The examiner may deem these documents to be relevant to patentability of the claims of the above-identified application. Copies of the documents are enclosed for the examiner's convenience.

The submission of the listed documents is not intended as an admission that any of the documents constitute prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the listed documents be considered by the examiner and be made of record in the present application and that initialed copies of Forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

It is understood that no fee is necessary for submission of this Information Disclosure Statement, as it is being filed before the later of three months from the filing date or the mailing of the first Office Action on the merits.

OIPE JC109
JUL 12 2004
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The Commissioner is hereby authorized to charge payment of any fees associated with this application or credit any overpayment to Deposit Account No. 02-4270.

Respectfully submitted,

Leslie Gladstone Restaino
Reg. No. 38,893
Attorney for Applicants
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/680,988
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First Named Inventor	Andrew R. Marks
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Examiner Name	to be assigned
Attorney Docket Number	5199-119

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 2004/0048780A1	03-11-2004	Andrew Marks	
		US- 2003/0134331A1	07-17-2003	Marks, et al.	
		US- 6,489,125B1	12-03-2002	Marks, et al.	
		US- 5,416,066	05-16-1995	Kaneko, et al.	
		US- 5,910,494	02-22-1996	Lawrence E. Brieaddy	
		US- 3,367,930	02-06-1968	Schmutz, et al.	
		US- 5,859,240	01-12-1999	Lawrence E. Brieaddy	
		US- 5,817,652	08-18-1994	Brieaddy, et al.	
		US- 5,723,458	08-18-1994	Brieaddy, et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		JP11199574	07-27-1999	Harada, et al.		
		JP4230681	08-19-1992	Kaneko, N.		
		JP10045706	02-17-1998	SUMITOMO SEIKA		
		WO02/051232A2	07-04-2002	Fischli, W.		
		WO92/12148	07-23-1992	Kaneko, N.		
		WO02/051838A1	07-04-2002	Aissaoui, et al		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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		US-			
		US-			
		US-			
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		WO97/03986	02-06-1997	Tanaka, et al.		
		WO03/034980A2	05-01-2003	Picariello, T.	// of 4662	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 15

Complete if Known	
Application Number	10/680,988
Filing Date	10/07/03
First Named Inventor	Andrew R. Marks
Art Unit	1646
Examiner Name	to be assigned
Attorney Docket Number	5199-119

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Antos et al., Dilated cardiomyopathy and sudden death resulting from constitutive activation of protein kinase A.	
		Circ. Res., 89:997-1004, 2001	
		Barbone et al., Comparison of right and left ventricular responses to left ventricular assist device support in patients with severe heart failure:	
		a primary role of mechanical unloading underlying reverse remodeling.	
		Circulation, 104:670-675, 2001	
		Bennett et al., Identification and characterization of the murine FK506 binding protein (FKBP) 12.6 gene.	
		Mamm. Genome, 9:1069-1071, 1998	
		Brillantes et al., Stabilization of calcium release channel (ryanodine receptor) function by FK506-binding protein.	
		Cell, 77:513-523, 1994	

Examiner Signature		Date Considered	

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		Bristow et al., Decreased catecholamine sensitivity and beta-adrenergic-receptor density in failing human hearts.	
		N. Engl. J. Med., 307:205-211, 1982	
		Cameron et al., FKBP12 binds the inositol 1,4,5-trisphosphate receptor at leucine-proline (1400-1401) and anchors calcineurin to this FK506-like	
		domain.	
		J. Biol. Chem., 272:27582-27588, 1997	
		Chen et al., Mechanism of TGFbeta receptor inhibition by FKBP12.	
		EMBO J., 16:3866-3876, 1997	
		Eichhorn and Bristow, Medical therapy can improve the biological properties of the chronically failing heart. A new era in the treatment of	
		heart failure.	
		Circulation, 94:2285-2296, 1996	

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		Fabiato, A., Calcium-induced release of calcium from the cardiac sarcoplasmic reticulum.	
		Am. J. Physiol., 245:C1-C14, 1983	
		Fozzard, H.A., Afterdepolarizations and triggered activity.	
		Basic Res. Cardiol., 87:105-113, 1992	
		Gillo et al., Calcium influx in induced differentiation of murine erythroleukemia cells.	
		Blood, 81:783-792, 1993	
		Jayaraman et al., Regulation of the inositol 1,4,5-trisphosphate receptor by tyrosine phosphorylation.	
		Science, 272:1492-1494, 1996 (N/A)	
		Jayaraman et al., FK506 binding protein associated with the calcium release channel (ryanodine receptor).	
		J. Biol. Chem., 267:9474-9477, 1992	

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		Kaftan et al., Effects of rapamycin on ryanodine receptor/Ca (2+)-release channels from cardiac muscle.	
		Circ. Res., 78:990-997, 1996	
		Laitinen et al., Mutation of the cardiac ryanodine receptor (RyR2) gene in familial polymorphic ventricular tachycardia.	
		Circulation, 103:485-490, 2001	
		Leenhardt et al., Catecholaminergic polymorphic ventricular tachycardia in children: a 7-year follow-up of 21 patients.	
		Circulation, 91:1512-1519, 1995	
		Marban et al., Mechanisms of arrhythmogenic delayed and early afterdepolarizations in ferret ventricular muscle.	
		J. Clin. Invest., 78:1185-1192, 1986	
		Marks A.R., Cellular functions of immunophilins.	
		Physiol. Rev., 76:631-649, 1996	

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		Marks et al., Progression of heart failure: is protein kinase a hyperphosphorylation of the ryanodine receptor a contributing factor?	
		Circulation, 105:272-275, 2002	
		Marx et al., Coupled gating between individual skeletal muscle Ca2+ release channels (ryanodine receptors).	
		Science, 281:818-821, 1998	
		Marx et al., PKA phosphorylation dissociates FKBP 12.6 from the calcium release channel (ryanodine receptor): defective regulation in failing hearts.	
		Cell, 101:365-376, 2000	
		Nabauer et al., Regulation of calcium release is gated by calcium current, not gating charge, in cardiac myocytes.	
		Science, 244:800-803, 1989	
		Ono et al., Altered interaction of FKBP 12.6 with ryanodine receptor as a cause of abnormal Ca(2+) release in heart failure.	
		Cardiovasc. Res., 48:323-331, 2000	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 15

Complete if Known	
Application Number	10/680,988
Filing Date	10/07/03
First Named Inventor	Andrew R. Marks
Art Unit	1646
Examiner Name	to be assigned
Attorney Docket Number	5199-119

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Priori et al., Clinical and molecular characterization of patients with catecholaminergic ventricular tachycardia.	
		Circulation, 106:69-74, 2002	
		Priori et al., Mutations in the cardiac ryanodine receptor gene (hRyR2) underlie catecholaminergic polymorphic ventricular tachycardia.	
		Circulation, 103:196-200, 2001	
		Reiken et al., Beta-adrenergic receptor blockers restore cardiac calcium release channel (ryanodine receptor) structure and function in heart failure.	
		Circulation, 104:2843-2848, 2001	
		Reiken et al., Beta-blockers restore calcium release channel function and improve cardiac muscle performance in human heart failure.	
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		Semsarian et al., The L-type calcium channel inhibitor diltiazem prevents cardiomyopathy in a mouse model.	
		J. Clin. Invest., 109:1013-1020, 2002	

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Sheet 7 of 15

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		Song and Belardinelli, ATP promotes development of afterdepolarizations and triggered activity in cardiac myocytes.	
		Am. J. Physiol., 267:H2005-2011, 1994	
		Swan et al., Arrhythmic disorder mapped to chromosome 1q42-q43 causes malignant polymorphic ventricular tachycardia in structurally	
		normal hearts.	
		J. Am. Coll. Cardiol., 34:2035-2042, 1999	
		Wehrens et al., FKBP12.6 deficiency and defective calcium release channel (ryanodine receptor) function linked to exercise-induced sudden	
		cardiac death.	
		Cell, 113:829-840, 2003	

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Sheet 8 of 15

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		Wit and Rosen, Pathophysiologic mechanisms of cardiac arrhythmias.	
		Am. Heart J., 106:798-811, 1983	
		Yano et al., Altered stoichiometry of FKBP12.6 versus ryanodine receptor as a cause of abnormal Ca(2+) leak through ryanodine receptor	
		in heart failure.	
		Circulation, 102:2131-2136, 2000	
		Bennett, et al., Synthesis of 2-methoxydibenzo[b,f](1,4)-thiazepin-11(10H)-one 5,5-dioxide.	
		Organic Preparations and Procedures International. 6(6):287-293, 1974 (N/A)	
		Callaway, C., et al., Localization of the High and Low Affinity [3H] Ryanodine Binding Sites on the Skeletal Muscle Ca2+ Release Channel.	
		The Journal of Biological Chemistry, 269:15876-15884, 1994	

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Sheet 9 of 15

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		Catsoulacos, Synthesis of substituted dihydrobenzothiazepines and related compounds.	
		J. Heterocyclic chemistry. 7(2): 409-411, 1970 (N/A)	
		Fodor, et al., New convenient synthesis of 1,4-benzothiazepines.	
		Tetrahedron Letters. 36 (5):753-756, 1995 (N/A)	
		Inagaki, et al., The cardioprotective effects of a new 1,4-benzothiazepine derivative, JTV519, on ischemia / reperfusion induced calcium overload in	
		isolated rat hearts.	
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		Br. J. Pharmacol. 130(4):767-776, 2000	

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		Kawabata, et al., Effect of a novel cardioprotective agent, JTV-519, on metabolism, contraction and relaxation in the ischemia reperfused rabbit heart.	
		Jpn. Circ. J. 64(10):772-776, 2000	
		Kawabata, et al., A novel cardioprotective agent, JTV 519, is abolished by nitric oxide synthase inhibitor on myocardial metabolism in ischemia-	
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		Kiriyama, et al., Effects of JTV-519, a novel anti-ischemic drug, on the delayed rectifier K+ current in guinea pig ventricular myocytes.	
		Naunyn Schmiedebergs Arch Pharmacol. 361(6):646-653, 2000	
		Kumagai, et al., Antiarrhythmic Effects of JTV-519, a Novel Cardioprotective Drug, on Atrial Fibrillation / Flutter in a Canine Sterile	
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		J. Cardiovasc. Electrophysiol. 14(8):880-884, 2003 (N/A)	

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		Am. J. Physiol. Heart Circ. Physiol. 284(3):1035-1042, 2003	
		Marks A. R., et al., Involvement of the cardiac ryanodine receptor / calcium release channel in catecholaminergic ventricular tachycardia	
		(familial polymorphic ventricular tachycardia)	
		J. Cellular Physiology 190: 1-6, 2001	
		Marks A. R., et al., Involvement of the cardiac ryanodine receptor / calcium release channel in catecholaminergic polymorphic ventricular	
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		Circulation. 106:8, 2002	
		Marks, Ryanodine receptors, FKBP12, and heart failure.	
		Frontiers in Bioscience 7: 970-977, 2002	
		Marks, et al., Progression of Heart Failure.	
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		Marx, S. O., et al., Coupled Gating Between Cardiac Calcium Release Channels (Ryanodine Receptors)	
		Circ. Res. 88: 1151-1158, 2001	

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		Nakaya, et al., Inhibitory Effects of JTV-519, a novel cardioprotective drug, on potassium currents and experimental atrial fibrillation in guinea	
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		Br. J. Pharmacol. 131(7):1363-1372, 2000	
		Reiken, S., et al., PKA phosphorylation of the cardiac calcium release channel (ryanodine receptor) in normal and failing hearts: role of phosphatases and	
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		Circulation, 107:2459-2466, 2003	
		Shibuta, 264W94, Current Opinion in Cardiovascular, Pulmonary and Renal Investigational Drugs. 1(2): 276-278, 1999 (N/A)	
		Shinohara, A synthesis of mono- and dimethoxy-1,2,3,4-tetrahydroisoquinolines via Pummerer reaction: effects	
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		Chemical and Pharmaceutical Bulletin. 46(6):918-927, 1998	
		Szabo, et al., Synthesis and Transformation of 4,5-dihydro-1,4-benzothiazepin-3(2H)-one derivatives.	
		Magyar Kemiai Folyoirat. 93(3):139-144, 1987 (N/A)	

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Application Number	10/680,988
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First Named Inventor	Andrew R. Marks
Art Unit	1646
Examiner Name	to be assigned
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Szabo, et al., Synthesis and spectroscopic investigation of 1,4-benzothiazepine derivatives.	
		Magyar Kemiai Folyoirat. 93(6):269-276, 1987 (N/A)	
		Szabo, et al., Saturated heterocycles.	
		Canadian Journal of Chemistry. 65(1), 175-181, 1987 (N/A)	
		Tse and Lam, JTV-519 Japan Tobacco.	
		Curr. Opin. Investig. Drugs. 2(7):936-939, 2001 (N/A)	
		Wehrens, et al., FKBP12.6 deficiency and defective calcium release channel (ryanodine receptor) function linked to exercise-induced sudden cardiac death.	
		Cell 113 (7):829-840, 2003	
		Yano, et al., FKBP12.6 Mediated Stabilized of calcium Release Channel (Ryanodine Receptor) as a Novel Therapeutic Strategy Against Heart Failure.	
		Circulation. 107:477, 2003	

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